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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,035	10/31/2003	John Francis Bateman	A36056-PCT-USA-A	3842

21003 7590 04/02/2007

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EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
04/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/699,035	Applicant(s) BATEMAN ET AL.	
	Examiner Maher M. Haddad	Art Unit 1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 March 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *None*.
   Claim(s) objected to: *None*.
   Claim(s) rejected: *4,5,12,43 and 44*.
   Claim(s) withdrawn from consideration: *None*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because:

1. Claims 4-5, 12 and 43-44 stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to used the claimed invention for the same reasons set forth in the previous Office Action mailed 12/21/06

Applicant's arguments, filed 3/21/07, have been fully considered, but have not been found convincing.

Applicant submits that the WARP has a utility as a histological marker.

However, applicants' specification lack information regarding a correlative or causal relationship between the WARP in normal ECM and abnormal of ECM. Again, Is WARP elevated or decreased? The killed artisan would not know how to use WARP polypeptides to predict integrity? The specification fails to determine the function of WARP. WARP as a molecular marker has failed to fulfill the requirements of a diagnostic and prognostic assessment. Further using WARP as histological marker of the integrity of the extracellular matrix is a generic utility that can be applied to several proteins such as type X Collagen, ALP, OP, MGP among other. In other words, without knowledge of the target's function of WARP protein, the claimed invention lacks a specific function. The specification does not disclose that the claimed genes are markers for specific diseases.

Further, while the claims are drawn to polypeptides of WARP, neither the instant specification or the art of record identifies even a single disease or disorder which has been shown to be associated with the claimed SEQ ID NO: 5 of the instant invention has not been shown to be differentially expressed in any disease or disorder, the claimed polypeptide cannot be employed in a diagnostic capacity. The increased copy number of DNA does not provide a readily apparent use for the polypeptide, for which there is no information regarding level of expression, activity, or role in the integrity of ECM.

Further, the issues of % similarity hybridization remains for the same reasons set forthe in the previous Office Action.

2. Claims 4-5, 12 and 43-44 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the same reasons set forth in the previous Office Action mailed 12/21/06.

Applicant's arguments, filed 3/21/07, have been fully considered, but have not been found convincing.

With respect to the claimed features of "95% homology" and "99% homology," Applicants rsubmit that the specification provides support for the terms. The specification in paragraph [0051] defines "homolog" as including "an analogous polypeptide having at least about 65% similar amino acid sequence from another animal species or from a different locus within the same species." Further, as disclosed in paragraph [0144] of the specification, "[t]he human homolog of WARP was identified by searching the genome data with the mouse WARP protein sequence. A match with a predicted protein sequence (hypothetical protein FLJ22215) with very high homology to the mouse WARP was found ....These sequences are clearly homologs of each other because they share 79% amino acid identity (see FIG. 1C). In addition, if conserved changes are considered in the analysis, they share 95% identity."

However, there is no described or art-recognized correlation or relationship between the structure of the invention, the Willebrand domain of the WARP and it's ECM function, the feature deemed essential to the instant invention. Therefore, one of skill in the art would not envisage, based on the instant disclosure, the claimed variants of 95% or 99% similarity to SEQ ID NO: 5 which retain the features essential to the instant invention.

Maher M. Haddad

MAHER M. HADDAD
PRIMARY EXAMINER